

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed January 14, 2010. Claims 1-22 were pending, claims 4 and 11 were previously withdrawn, and claims 1-3, 5-10, and 12-22 were rejected in view of cited art.<sup>1</sup> Claims 1, 17, and 20 are amended, with claims 1-22 pending and claims 4 and 11 being previously withdrawn.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. PRIOR ART REJECTIONS**

#### **I. REJECTION UNDER 35 U.S.C. § 103**

As presented herein for reconsideration (see independent claim 1, as exemplary), the invention of independent claim 1 comprises a method for delivering a closure element to seal an opening through tissue beneath a patient's skin. The closure element associated with the method is carried by a carrier assembly slidable on an outer surface of an elongate member, the elongate member comprising a skin overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and at least partially overlying the carrier assembly. The elongate member is provided with a locator member slidably associated therewith, the locator member having one or more expandable positioning elements on its distal portion.

The method includes inserting the distal end of the elongate member through the patient's skin and into an opening through tissue and advancing the locator member distally from the

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<sup>1</sup> Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

distal end of the elongate member. The one or more positioning elements of the locator member are expanded and then the locator member is withdrawn until the positioning elements contact tissue. Following locating the positioning elements in contact with the tissue, the carrier assembly carrying the closure element is advanced towards the distal end of the elongate member from a location distal the patient's skin and distal the opening through tissue. The carrier assembly separates the skin from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin as the carrier assembly is advanced towards the distal end. The method further includes deploying the closure element from the carrier assembly within the opening to substantially seal the opening.<sup>2</sup>

The Office Action rejected claims 1-3, 5, 7-10, and 14-22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,674,231 (*Green*) in view of U.S. Patent No. 6,447,540 (*Fontaine*). Claims 12-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Fontaine*, as applied to claim 1, and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Fontaine*, as applied to claim 1, and further in view of U.S. Patent No. 5,868,755 (*Kanner*). Applicant traverses the Examiner's rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims.

Applicant respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Green* either singly or in combination with any other reference of record.<sup>3</sup> In particular, *Green* discloses that "in use, the elongated body 20 of surgical apparatus 10 is introduced into the interior lumen 102 of blood vessel 104 through a conventional cannula 100" (col. 7, ll. 18-20). "Thereupon, locator 60 is moved distally

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<sup>2</sup> The other two independent claims (e.g. claims 17 and 20) are similar.

Claim 17 includes the limitation of "following locating one or more positioning elements of a locator member in contact with the tissue and locating said distal end of the elongate member, advancing the carrier assembly carrying the closure element towards the distal end of the elongate member from a location distal the patient's skin and distal the opening through tissue . . ."

Claim 20 includes limitation of "following locating one or more positioning elements of a locator member in contact with the tissue, advancing the carrier assembly carrying the closure element towards the distal end of the elongate member from a location distal the patient's skin and distal the opening through tissue."

<sup>3</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

. . . [such that] locator 60 is advanced from its proximal-most position disposed with the axial bore 34a of clip support fixture 34 to its distal-most position extending from the distal end of clip support fixture 34” (Id. at ll. 23-29). “At such a time, the arcuate expansion portions . . . remain in a collapsed (stressed) condition restrained within the interior lumen of cannula 100” (Id. at ll. 29-33). To deploy the locator 60, the cannula 100 is withdrawn and “the arcuate expansion portions 62b and 64b of locator arms 62 and 64 move into their deployed (unstressed) positions” as illustrated in FIG. 15 (Id. at ll. 41-43). Once the locator is positioned, the surgical clip is deployed as the, “pusher tube 42 is driven distally, urging surgical clip 22 in a distal direction” so that “the opposing clip legs 24a and 24b of surgical clip 22 are moved to an open position as the clip translates with respect to camming ramps 40a and 40b, as illustrated in FIGS. 17 and 18” (col. 7, ln. 63-col. 8, ln. 2). As illustrated in FIG. 15, the surgical clip 22 is in close proximity to the blood vessel 104. No mention is made of the pusher tube 42 moving the surgical clip from a position outside of the patient once the locator is deployed.

By contrast to the teaching of Green, independent claim 1 recites, in part, “inserting the distal end of the elongate member through the patient’s skin and into an opening through tissue” and “following locating said positioning elements [of the locator] in contact with the tissue, advancing the carrier assembly carrying the closure element towards the distal end of the elongate member from a location distal the patient’s skin and distal the opening through tissue, the carrier assembly separating the skin from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin as the carrier assembly is advanced towards the distal end.” Green neither teaches nor suggests “following locating said positioning elements [of the locator] in contact with the tissue, advancing the carrier assembly carrying the closure element towards the distal end of the elongate member from a location distal the patient’s skin and distal the opening through tissue.”

Accordingly, for at least the reasons noted, independent claims 1, 17, and 20 and the claims depending therefrom<sup>4</sup> are neither anticipated nor made obvious by *Green*, either singly or in combination with any other cited prior art of record<sup>5</sup>, and thus reconsideration and withdrawal of the rejection under Section 103 is respectfully requested.

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<sup>4</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 2, 3, 5-10, and 12-16, 18-19, and 21-22, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicant thus does not acquiesce in any asserted rejections of the dependent claims 2, 3, 5-10, and 12-16, 18-19, and 21-22.

**C. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 12th day of May, 2010.

Respectfully submitted,

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<sup>5</sup> *Fontaine*, *Martinez*, and *Kanner* were cited as secondary references. *Fontaine* was cited for the proposition that it discloses "a skin or sleeve 16 with a weakened region overlying at least a portion of an outer surface between a carrier assembly 20 and a distal end of an elongate member 12 and the carrier assembly may cause the skin to separate or split . . ." and "a slippery surface on the sleeve" (Office Action, pp. 3 and 4). *Martinez* was cited for the proposition that it discloses "a skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced . . ." and *Kanner* was cited for the proposition that it discloses "a skin being bonded to the outer surface of the elongate member by and adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface." (Office Action, pp. 5 and 6) That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Green*. Thus, even assuming *arguendo* that any of the references to *Fontaine*, *Martinez*, and *Kanner* are properly combinable with *Green*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Green*.